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DAC

Atty Dkt No. 098810-0278740
Pat. App. Ser. No. 09/813,463

1646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Warren, et al.

Group Art Unit: 1653

Serial No.: 09/813,463

Examiner: Olga Chernyshev, Ph.D.

Filed: March 20, 2001

Title: PEPTIDE SPECIFICITY OF ANTI MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS

TRANSMITTAL LETTER

Certificate of Mailing Under 37 C.F.R. §1.8
I hereby certify that this correspondence along with any paper referred to as being attached is being Mailed to Addressee by service of the United States Postal Service addressed to Commissioner for Patents, P.O. Box, 1450, Alexandria, VA 22313-1450

Date: May 24, 2004 By: _____
Sachiko Y. Snedden

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

Transmitted herewith for filing are the following:

1. Petition under 37 C.F.R. §1.181(a) to Withdraw the Holding of Abandonment;
2. Copies of: Response to Office Action and other documents timely filed on December 1, 2003;
3. Copy of Postcard Receipt date stamped December 4, 2004, by the U.S. Patent and Trademark Office; and
4. Return Postcard.

No fee is due for filing this Petition; however, the Commissioner is hereby authorized to charge any fee that may be due in connection with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-2212.

Respectfully submitted,

Pillsbury Winthrop LLP

Date: May 24, 2004

By _____
Robert M. Bedgood, Ph.D.
Reg. No. 43,488

11682 El Camino Real
Suite 200
San Diego, CA 92130-2092
(619) 234-5000

Tel. No. (858) 509-4065
Fax No. (858) 509-4010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Warren, et al.

Group Art Unit: 1653

Serial No.: 09/813,463

Examiner: Olga Chernyshev, Ph.D.

Filed: March 20, 2001

Title: PEPTIDE SPECIFICITY OF ANTI MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS

PETITION UNDER 37 C.F.R. §1.181(A) TO WITHDRAW HOLDING OF ABANDONMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Certificate of Mailing Under 37 C.F.R. §1.8

I hereby certify that this correspondence along with any paper referred to as being attached is being Mailed to Addressee by service of the United States Postal Service addressed to Commissioner for Patents, P.O. Box, 1450, Alexandria, VA 22313-1450

Date: May 24, 2004 By: _____
Sachiko Y. Snedden

Sir or Madam:

In response to the Notice of Abandonment mailed April 22, 2004, Applicants respectfully petition to withdraw the holding of abandonment for the above-identified application because a Response to the Office Action mailed May 29, 2003, was timely filed:

1. On December 1, 2003, Applicant's representative filed a Response to the Office Action mailed May 29, 2003, and fee and petition for extension of time. The Response with a petition for a 3 month extension of time was due on December 1, 2003, since November 29, 2003, fell on a Saturday.
2. A Certificate of Mailing under 37 C.F.R. §1.8 executed by Patricia Munoz indicating that the Response was filed on December 1, 2003, appears on the first page of the Response, a copy of which is attached herewith.

3. Attached is a copy of the postcard receipt for the Response filed December 1, 2003, date stamped on December 4, 2003, by the U.S. Patent and Trademark Office.
4. Applicant's representative also filed via facsimile on April 15, 2004, a Statement of Submission of true copies of the Response filed December 1, 2003, in response to the Examiner's telephone call to the undersigned.

In view of the foregoing evidence indicating that a response to the Office Action mailed May 29, 2003, was timely filed December 1, 2003, Applicants respectfully request that the holding of abandonment for the above-identified application be withdrawn. No fee is due for filing this Petition; however, the Commissioner is hereby authorized to charge any fee that may be due in connection with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-2212.

Respectfully submitted,

Pillsbury Winthrop LLP

Date: May 24, 2004

By _____
Robert M. Bedgood, Ph.D.
Reg. No. 43,488

Tel. No. (858) 509-4065
Fax No. (858) 509-4010

11682 El Camino Real
Suite 200
San Diego, CA 92130-2092
(619) 234-5000

PAT-103 5/02 PTO RECEIPT FOR INDICATED ITEMS Atty RMB

Appln. No: 09/813,463 Date: 12/0103

Inventor(s) Warren, et al C# 098810

Title: PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS M# 0278740

ENCLOSED:

☒ Response to Office Action dated 5/29/03 ☐ Appendix ☐ Cover sheet

☐ Declaration (3 #pgs)

☐ Assignment ☐ Cover Sheet

#___ No. of Priority Documents

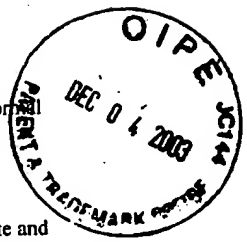
#2 No. Sheets Replacement Drawings (Fig(s) 11A to 11D) ☐ 1 set Formal

☐ IDS Letter ☐ cited Appl(s). ☐ Foreign sch rept./OA

☐ PTO-1449 ☐ cited docs.

$518.00 - PLEASE CHARGE DEPOSIT ACCOUNT NO. 50-2212

Other: Reply/Amendment/Letter (in duplicate); Sequence Listing (diskette and paper copy); Statement under 37 C.F.R. § 1.821 in support of Sequence Listing; and Return Postcard



PAT-103 5/02 PTO RECEIPT FOR INDICATED ITEMS Atty RMB
Appln. No: 09/813,463 Date: 12/0103
Inventor(s) Warren, et al C# 098810
Title: PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS M# 0278740
ENCLOSED:
☒ Response to Office Action dated 5/29/03 ☐ Appendix ☐ Cover sheet
☐ Declaration (3 #pgs)
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#___ No. of Priority Documents
2 No. Sheets Replacement Drawings (Fig(s) 11A to 11D) ☐ 1 set Formal
☐ IDS Letter ☐ cited Appl(s). ☐ Foreign sch rept./OA
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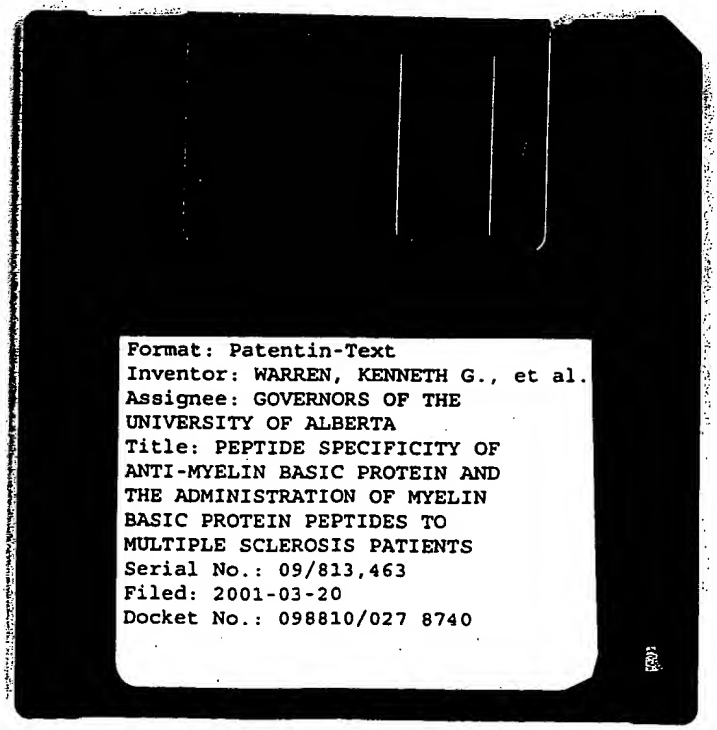
$518.00 - PLEASE CHARGE DEPOSIT ACCOUNT NO. 50-2212
Other: Reply/Amendment/Letter (in duplicate); Sequence Listing (diskette and paper copy); Statement under 37 C.F.R. § 1.821 in support of Sequence Listing; and Return Postcard



Certificate of Mailing Under 37 C.F.R. §1.8

I hereby certify that this correspondence and any paper referred to as being attached or enclosed is being mailed via "First Class Mail" of the United States Postal Service on the date shown below in an envelope addressed to: Mail Stop Amendment - Fee, Commissioner for Patents, P.O. Box 1450 , Alexandria, VA, 22313-1450.

Dated: December 1, 2003

By: Patricia Muñoz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Group Art Unit 1646
Examiner: Chernyshev, O.
Atty. Dkt. 098810/0278740 (C-M) | 92021 (US) (Client Ref)

Inventor(s): Warren, et al.
Appln. No.: 09 (Series Code ↑) | 813,463 (Serial No. ↑)

Appln. Title: PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS

Filed: March 20, 2001
Mail Stop: Fee - Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Date: December 1, 2003

REPLY/AMENDMENT/LETTER

This is a reply/amendment/letter in the above-identified application and includes the herewith attachment of same date and subject which is incorporated hereinto by reference and the signature below is treated as the signature to the attachment in absence of a signature thereto.

FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity claim
A. ☐ NOT made
B. ☐ Withdrawn
C. ☐ made herewith
D. ☒ made previously
For B & C See Required Separate Paper (Pat-256)

	Claims remaining after amendment	Highest number previously paid for		Present Extra	Large/Small Entity	Additional Fee	Fee Code Lg/Sm
2. Total Effective Claims	8	**minus	20	0	x $18/$9 =	+ $0	1202/2202
3. Independent Claims	4	***minus	3	1	x $86/$43 =	+ $43	1201/2201
4. If amendment enters proper multiple dependent claim(s) into this application for first time (leave blank if this is a reissue application) ..... add					+ $290/$145 =	+ $0	1203/2203
5. Original due Date: August 29, 2003	☐ NONE						
6. Petition is hereby made to extend the original due date to cover the date this response is filed for which the requisite fee is attached			(1 mo)	$110/$55 =	+ $475		1251/2251
			(2 mos)	$420/$210 =			1252/2252
			(3 mos)	$950/$475 =			1253/2253
			(4 mos)	$1,480/$740=			1254/2254
			(5 mos)	$2,010/$1,005=			1255/2255
7. Enter any previous extension fee paid since above original due date and subtract					- $0		
					Extension Fee	+ $475	
8.					+ $110/$55	+ $0	1814/2814
9. If Terminal Disclaimer attached, add Rule 20(d) official fee					+ $180	+ $0	1806
10. If IDS attached requires Official Fee under Rule 97 (c), ... add					+ $180		1806
or if Rule 97(d) Request					+ $770/385	+ $0	1809/2809
11. After-Final Request Fee per rules 129(a) and 17(r)					x $770/385 ea	+ $0	1810/2810
12. No. of additional inventions for examination per Rule 129(b)					+ $770/385	+ $0	1801/2801
13. Request for Continued Examination (RCE)							

14. Petition fee for	+ $0	
15. **Also attached:** Replacement Sheets for Figures 11A through 11D; Sequence Listing (diskette and paper copy); Statement Under 37 C.F.R. § 1.821 in Support of Filing Sequence Listing; Exhibit A; and Return Postcard.	TOTAL FEE =	$518
		PLEASE CHARGE OUR DEP. ACCT

16. *If the entry in this space is less than entry in next space, the "Present Extra" result is "0".
17. **If the "Highest number previously paid for" in this space is less than 20, write "20" in this space.
18. ***If the "Highest number previously paid for" in this space is less than 3, write "3" in this space.

Our Deposit Account No. 50-2212
(Our Order No. 098810/0278740
C# M#

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficiencies only) now or hereafter relative to this application and the resulting Official Document under Rule 20, or credit any overpayment, to our Accounting/Order Nos. shown above, for which purpose a duplicate copy of this sheet is attached.
This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal sheet is filed.

Query: Is appeal deadline now? If so, file Notice of Appeals separately.

Pillsbury Winthrop LLP
Intellectual Property Group
By Atty: Robert M. Bedgood, Ph.D Reg. No. 43,488
Sig:
11682 El Camino Real
Suite 200
San Diego, CA 92130-2092
Tel: (619) 234-5000
Atty/Sec: RMB/pm
Fax: (858) 509-4010
Tel: (858) 509-4065

NOTE: File this cover sheet in duplicate with PTO receipt (PAT-103A) and attachments

Certificate of Mailing Under 37 C.F.R. §1.8

I hereby certify that this correspondence and any paper referred to as being attached or enclosed is being mailed via "First Class Mail" of the United States Postal Service on the date shown below in an envelope addressed to: Mail Stop Amendment - Fee, Commissioner for Patents, P.O. Box 1450 , Alexandria, VA, 22313-1450.

Dated: December 1, 2003

By: Patricia Muñoz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PATENT APPLICATION

Inventor(s): Warren, et al.
Appln. No.: 09 (Series Code ↑) 813,463 (Serial No. ↑)
Filed: March 20, 2001
Mail Stop: Fee - Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Group Art Unit 1646
Examiner: Chernyshev, O.
Atty. Dkt. 098810/0278740 (C-M) | 92021 (US) (Client Ref)

Appln. Title: **PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS**

Sir:

Date: December 1, 2003

REPLY/AMENDMENT/LETTER

This is a reply/amendment/letter in the above-identified application and includes the herewith attachment of same date and subject which is incorporated hereinto by reference and the signature below is treated as the signature to the attachment in absence of a signature thereto.

FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity claim
A. ☐ NOT made
B. ☐ Withdrawn
C. ☐ made herewith
D. ☒ made previously
For B & C See Required Separate Paper (Pat-256)

	Claims remaining after amendment	Highest number previously paid for		Present Extra	Large/Small Entity	Additional Fee	Fee Code Lg/Sm
2. Total Effective Claims	8	**minus	20	0	x $18/$9 =	+ $0	1202/2202
3. Independent Claims	4	***minus	3	1	x $86/$43 =	+ $43	1201/2201
4. If amendment enters proper multiple dependent claim(s) into this application for first time (leave blank if this is a reissue application) ..... add					+ $290/$145 =	+ $0	1203/2203
5. Original due Date: August 29, 2003 ☐ NONE							
6. Petition is hereby made to extend the original due date to cover the date this response is filed for which the requisite fee is attached			(1 mo)	$110/$55 =	+ $475		1251/2251
			(2 mos)	$420/$210 =			1252/2252
			(3 mos)	$950/$475 =			1253/2253
			(4 mos)	$1,480/$740=			1254/2254
			(5 mos)	$2,010/$1,005=			1255/2255
7. Enter any previous extension fee paid since above original due date and subtract					- $0		
					Extension Fee	+ $475	
8.					+ $110/$55	+ $0	1814/2814
9. If Terminal Disclaimer attached, add Rule 20(d) official fee					+ $180	+ $0	1806
10. If IDS attached requires Official Fee under Rule 97 (c), ... add					+ $180		1806
or if Rule 97(d) Request					+ $770/385	+ $0	1809/2809
11. After-Final Request Fee per rules 129(a) and 17(r)					x $770/385 ea	+ $0	1810/2810
12. No. of additional inventions for examination per Rule 129(b)					+ $770/385	+ $0	1801/2801
13. Request for Continued Examination (RCE)							

14. Petition fee for	+ $0	
15. **Also attached:** Replacement Sheets for Figures 11A through 11D; Sequence Listing (diskette and paper copy); Statement Under 37 C.F.R. § 1.821 in Support of Filing Sequence Listing; Exhibit A; and Return Postcard.	TOTAL FEE =	$518
		PLEASE CHARGE OUR DEP. ACCT

16. *If the entry in this space is less than entry in next space, the "Present Extra" result is "0".
17. **If the "Highest number previously paid for" in this space is less than 20, write "20" in this space.
18. ***If the "Highest number previously paid for" in this space is less than 3, write "3" in this space.

Our Deposit Account No. 50-2212
(Our Order No. C# 098810 M# /0278740

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficiencies only) now or hereafter relative to this application and the resulting Official Document under Rule 20, or credit any overpayment, to our Accounting/Order Nos. shown above, for which purpose a duplicate copy of this sheet is attached.
This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal sheet is filed.

Query: Is appeal deadline now? If so, file Notice of Appeals separately.

Pillsbury Winthrop LLP
Intellectual Property Group
By Atty: Robert M. Bedgood, Ph.D Reg. No. 43,488
Sig:
11682 El Camino Real
Suite 200
San Diego, CA 92130-2092
Tel: (619) 234-5000
Atty/Sec: RMB/pm
Fax: (858) 509-4010
Tel: (858) 509-4065

NOTE: File this cover sheet in duplicate with PTO receipt (PAT-103A) and attachments

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Warren et al.	)	Examiner: Olga Chernyshev, PhD
Serial No.: 09/813,463	)	Art Unit: 1653
Filed: March 20, 2001	)	
Title: PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS	)	

RESPONSE TO OFFICE ACTION

Commissioner of Patents
United States Patent and Trademark Office
Box 1450
Washington, D.C. 22313-1450

Sir:

In response to the Official Action mailed May 29, 2003, the time for responding having been extended to December 1, 2003 (November 29 fell on a Saturday) by the accompanying fee and petition under 37 C.F.R. §1.136, Applicants respectfully request consideration of the following amendments and remarks:

Amendments to the **Specification** begin at **page 2.**

Amendments to the **Claims** begin at **page 5.**

Remarks begin at **page 7.**

Certificate of Mailing Under 37 C.F.R. §1.8

I hereby certify that this correspondence and any paper referred to as being attached or enclosed is being mailed via "First Class Mail" of the United States Postal Service on the date shown below in an envelope addressed to: Mail Stop Amendment - Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450.
Dated: December 1, 2003

By: Patricia Muñoz

IN THE SPECIFICATION:

Please amend the specification as follows:

At page 5, line 14, please insert a sequence identifier as follows:

--R_1-Val-His-Phe-Phe-Lys-Asn-Ile-R_2 (SEQ ID NO:2)--

At page 5, line 23, please insert sequence identifiers as follows:

--Examples of said peptides are selected from (SEQ ID NOS:3 to 13):--

At page 9, line 15, please substitute an upper case letter as follows:

--Fig 11[[a]]A shows free--

At page 9, line 19, please substitute an upper case letter as follows:

--Fig 11[[b]]B shows free--

At page 9, line 24, please substitute the corresponding phrase with the following:

--Fig 11[[c]]C shows free--

At page 9, line 28, please substitute the corresponding phrase with the following:

--Fig 11[[d]]D shows free--

At page 12, line 14, please insert a sequence identifier as follows:

--R_1-Val-His-Phe-Phe-Lys-Asn-Ile-R_2 (SEQ ID NO:2)--

At page 12, line 31, please insert a sequence identifier as follows:

--R_1-Val-His-Phe-Phe-Lys-Asn-Ile-R_2 (SEQ ID NO:2)--

At page 13, line 12, please substitute the corresponding sequence identifier as follows:

~~--SEQID No:1~~ SEQ ID NO:1--

At page 13, line 17, please substitute the corresponding sequence identifier as follows:

~~–SEQID No:1~~ SEQ ID NO:1--

At page 13, lines 20-21, please insert a sequence identifier as follows:

–Val-His-Phe-Phe-Lys-Asn-Ile (SEQ ID NO:2)--

At page 15, line 1, please substitute sequence identifier "SEQ ID NO:1" as follows:

~~–SEQ ID NO:1~~ SEQ ID NO:14 (amino acids 61 to 106 of SEQ ID NO:1)--

At page 15, line 7, please insert sequence identifiers as follows:

--Examples of peptides are selected from the group consisting of (SEQ ID NOS:5, 4, 6, 3, 7 and 8, respectively):--

At page 15, line 25, please insert a sequence identifier as follows:

--R_1-Val-His-Phe-Phe-Lys-Asn-Ile-R_2 (SEQ ID NO:2)--

At page 16, line 1, please insert sequence identifiers as follows:

--Examples of peptides are selected from (SEQ ID NOS:9 to 13):--

At page 20, lines 21-23, please capitalize the trademark as follows:

--IgG was purified from concentrated CSF of patients with acute MS by protein A-Sepharose (~~Pharmacia~~ PHARMACIA™) affinity chromatography as previously described--

At page 20, lines 29-30, please capitalize the trademark as follows:

--Purified MBP was coupled to CNBr-activated Sepaharose 4B (~~Pharmacia~~ PHARMACIA™) according to the manufacturer's instructions--

At page 35, lines 11-12, please substitute an upper case letter as follows:

--One of these patients (Figure 11[[a]]A) received--

At page 35, line 24, please substitute an upper case letter as follows:

--four daily injections (Figure 11[[b]]B: it#1, it#2, it#3, it#4)--

At page 36, line 2, please substitute an upper case letter as follows:

-- Figure 11[[c]]C illustrates the anti-MBP profile--

At page 36, line 13, please substitute an upper case letter as follows:

-- injection (Figure 11[[d]]D: it#1, it#2, it#3, it#4) and 10 days--

IN THE CLAIMS:

Please amend the claims and add new claims as follows:

18. (Amended) A method of predicting therapeutic efficacy of treatment of a multiple sclerosis patient with a peptide of from ~~about 8 to about 25~~ 7 to 46 amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO:1, including substitutions, additions or deletions thereof, provided the peptide is capable of neutralizing or modulating the production of anti-myelin basic protein, comprising screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 ~~HLA-DR2~~ haplotype, wherein the presence of the human leukocyte antigen (HLA)-DR2 ~~HLA-DR2~~ haplotype in the patient is predictive of therapeutic efficacy of treatment with the peptide.

19. (Amended) The method of ~~any of claims 1 to 3~~ claim 18, wherein the human leukocyte antigen (HLA)-DR2 ~~HLA-DR2~~ haplotype comprises DRB1*1501 or DRB1*15021.

20. (Amended) The method of ~~any of claims 1 to 3~~ claim 18, wherein the patient has chronic progressive multiple sclerosis (MS) ~~MS~~.

21. (New) A method of predicting therapeutic efficacy of treatment of a multiple sclerosis patient with a peptide of from 7 to 46 amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO:1, comprising screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype, wherein the presence of the human leukocyte antigen (HLA)-DR2 haplotype in the patient is predictive of therapeutic efficacy of treatment with the peptide.

22. (New) A method of predicting therapeutic efficacy of treatment of a multiple sclerosis patient with a peptide of from 8 to 25 amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO:1, including substitutions, additions or

deletions thereof, provided the peptide is capable of neutralizing or modulating the production of anti-myelin basic protein, comprising screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype, wherein the presence of the human leukocyte antigen (HLA)-DR2 haplotype in the patient is predictive of therapeutic efficacy of treatment with the peptide.

23. (New) A method of predicting therapeutic efficacy of treatment of a multiple sclerosis patient with a peptide of from 8 to 25 amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO:1, comprising screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype, wherein the presence of the human leukocyte antigen (HLA)-DR2 haplotype in the patient is predictive of therapeutic efficacy of treatment with the peptide.

24. (New) A method of predicting therapeutic efficacy of treatment of a multiple sclerosis patient with a peptide having a sequence with the formula:
R_1-Val-His-Phe-Phe-Lys-Asn-Ile-R_2 (SEQ ID NO:2) and salts thereof, wherein R_1 and R_2 are independently selected from the group consisting of hydrogen, hydroxy, the residue of an amino acid and the residue of a polypeptide; provided that R_1 and R_2 are not both hydrogen or hydroxyl at the same time, comprising screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype, wherein the presence of the human leukocyte antigen (HLA)-DR2 haplotype in the patient is predictive of therapeutic efficacy of treatment with the peptide.

25. (New) The method of claim 24, wherein R_1 or R_2 is a naturally occurring amino acid.

REMARKS

This Response is being filed in connection with the Office Action mailed May 29, 2003. Claims 16 to 20 are pending. Claims 16 and 17 stand withdrawn from consideration as directed to a non-elected invention. New claims 21 to 25, directed to the elected invention of predicting therapeutic efficacy of treatment of a multiple sclerosis, have been added. Accordingly, upon entry of the Response claims 18 to 25 are under consideration.

Regarding the Amendments to the Specification

The specification has been amended to address various informalities. In particular, sequence identifiers (SEQ ID NO) have been corrected or inserted at pages 5, 12, 13, 15 and 16. In addition, trademarks have been capitalized. Replacement sheets for Figures 11A-11D are submitted herewith, and the specification has been amended where Figure 11 is referenced to recite upper case letters, A-D. Thus, as the amendments to the specification were made to address various informalities, no new matter has been added and entry thereof is respectfully requested.

Regarding the Claim Amendments

The claim amendments are supported throughout the specification or were made to address various informalities. In particular, the amendment to claim 18 to recite that treatment is with a peptide of from "7 to 45" amino acids is supported, for example, at page 12, lines 10-14, which discloses the smallest common region of the effective decapeptides is from amino acid 87 to 93, and a seven residue peptide having the formula R_1-Val-His-Phe-Phe-Lys-Asn-Ile-R_2; and at page 14, lines 17-21, which discloses peptides effective in down regulating anti-MBP that "correspond to the amino acid sequence of h-MBP from about residue 61 to about 106," which is 46 amino acids in length. Claims 19 and 20 have been amended to depend from claim 18 instead of claims 1 to 3 due to incorrect claim numbering in the Preliminary Amendment filed November 30, 2001, and the elected invention. The amendment to claims 18 and 19 to recite the term "human leukocyte antigen" for the abbreviation HLA was made in response to the

Examiner's request. The amendment to claim 20 to recite the term "multiple sclerosis" for the abbreviation MS was also made in response to the Examiner's request. Thus, as the amendments to the claims were made to address various informalities, no new matter has been added and entry thereof is respectfully requested.

Regarding the New Claims

New claims 21 to 25, directed to methods of predicting therapeutic efficacy of treatment of a multiple sclerosis patient with particular peptides in part included in claim 18, by screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype, are supported throughout the specification. In particular, claim 21 is supported as set forth above for the amendment to claim 18 and, for example, at page 42, line 1, to page 43, line 11, which discloses DR2 haplotypes of patients who have low or undetectable auto-antibody levels one year after a second iv MBP injection. Claim 21 is also supported, for example, at page 14, line 17, to page 15, line 6. Claims 22 and 23 are supported, for example, by claim 18. Claims 24 and 25 are supported, for example, at page 12, lines 11-26, and as set forth above for claim 21. Thus, as claims 21 to 25 are supported throughout the specification, no new matter has been added and entry thereof is respectfully requested.

Regarding the Filing Date and Priority Claim

The claim of priority of the subject application to U.S. Application Serial No. 09/055,263, now U.S. Patent No. 6,252,040, was objected to for allegedly lacking copendency between the subject application and the parent application. An incorrect filing date accorded to the subject application by the Patent Office is relied upon as grounds for this objection.

The filing date of the subject application is March 20, 2001. A brief chronology of events that lead the Patent Office to accord an incorrect filing date to the subject application follows. A Notice of Incomplete Non-Provisional Application was mailed by the Patent Office on November 29, 2001, alleging that no drawings were filed. In response, a Petition for Review of Notice of Incomplete Non-Provisional Application was filed on January 11, 2002, including

evidence that the Drawings had been filed March 20, 2001. Submitted with the Petition was a copy of the date-stamped return post-card indicating that Figures 1-18 were filed with the application on March 20, 2001. Unfortunately, although this Petition was timely received by the Patent Office (the Patent Office deducted the Petition fee from the deposit account), it has to date not been acted upon. Applicants have been in contact with the Petitions branch of the Patent Office and understand that the Petition for correcting the error in the filing date of the subject application is presently being acted upon.

Applicants also wish to bring to the Examiner's attention the fact that parent application serial no. 09/055,263 was expressly incorporated by reference in the subject continuation application at the time the subject application was filed (see the Rule 53(b) request for filing sheet submitted with the subject application March 20, 2001, attached herewith as Exhibit A). Item #3 of the request states that "The entire disclosure of the prior application is considered as being a part of the disclosure of the accompanying application and is hereby incorporated therein by reference thereto." Accordingly, as Figures 1 to 18 of the parent application are a part of the subject application filed on March 20, 2001, for this reason alone the subject application is entitled to the March 20, 2001, filing date.

In view of the foregoing, the subject application is entitled to a March 20, 2001, filing date. Because the subject application was filed prior to the issuance of the patent from parent application serial no. 09/055,263, the subject application's claim to the priority of application serial no. 09/055,263 under 35 U.S.C. §120 is proper.

Regarding the Drawings

The Drawings stand objected to due to absence of a capital letter in Figure 11. Submitted herewith is replacement sheets for Figure 11 in which lower case letters (a-d) have been replaced with upper case letters (A-D). In addition, the specification has been amended to reflect the change in letter case. Accordingly, in view of replacement Figure 11 and the amendments to the specification, the Drawings are in compliance with 37 C.F.R. §1.84, and particularly 37 C.F.R. §1.84(u)(1).

Regarding the Specification and Sequence Listing

The application allegedly fails to comply with the requirements for applications with sequences under 37 C.F.R. §§1.821-1.825. The Examiner requests that the sequences be identified and, if necessary, that substitute paper and computer readable copies of the Sequence Listing, and an amendment directing entry into the application, be submitted.

Applicants have amended the specification to insert sequence identifiers (SEQ ID NOs) as set forth above. In addition, submitted herewith are substitute paper and computer readable copies of the Sequence Listing under 37 C.F.R. §1.825. The substitute paper and computer readable copies of the Sequence Listing are identical and do not introduce new matter. An executed statement under 37 C.F.R. §§1.821(f) and (g) to that effect is submitted herewith.

The substitute Sequence Listing including the 170 amino acid human myelin basic protein (MBP) as SEQ ID NO:1 does not add new matter because, *inter alia*, this amino acid MBP sequence was disclosed in parent application serial no. 09/055,263 (now U. S. Patent No. 6,252,040; see column 25, SEQ ID NO:1), which was expressly incorporated by reference in the subject application (see the Rule 53(b) request for filing sheet, Item #3, attached herewith as Exhibit A). Accordingly, as the 170 amino acid MBP sequence of the parent application was a part of the subject application filed on March 20, 2001, inclusion of this MBP sequence in the substitute Sequence Listing does not introduce new matter. Thus, as the substitute Sequence Listing does not introduce new matter, entry thereof is respectfully requested.

Regarding the Claim Objections

Claims 19 and 20 stand objected to due to depending from claims 1 and 3. Applicants have amended claims 19 and 20 to depend from claim 18, due to the erroneous claim numbering submitted with the Preliminary Amendment filed November 30, 2001. In view of the amendment, Applicants respectfully request that the objection to claims 19 and 20 be withdrawn.

I. REJECTIONS UNDER 35 U.S.C. §112

The rejection of claims 18 to 20 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed. The grounds of rejection relate to 1) the alleged absence of a peptide from the specification; and 2) the recitation of "substitutions, additions or deletions" in the claims. As to the latter, allegedly the specification "fails to provide an adequate enabling disclosure for practicing such method of treatment."

Claims 18 and 20 are adequately enabled by the specification. Applicants first wish to point out that the subject application describes the full length human MBP protein, which is set forth as SEQ ID NO:1 in the sequence listing. Thus, the grounds for rejection due to the absence of this peptide from the specification should properly be withdrawn.

As to the second grounds of rejection, the preamble of claims 18 to 20 and 22 recite "predicting therapeutic efficacy of treatment of a multiple sclerosis patient with a peptide of from 7 to 46 (claims 18 to 20) or 8 to 25 (claim 22) amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO:1, including substitutions, additions or deletions thereof." The body of these claims recite how the method is performed, in particular, "screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype, wherein the presence of the human leukocyte antigen (HLA)-DR2 haplotype in the patient is predictive of therapeutic efficacy of treatment with the peptide." Thus, claims 18 to 20 and 22 do not require treatment of a multiple sclerosis patient. In fact, no treatment at all is being claimed. Thus, as treatment of a multiple sclerosis patient is not being claimed, treatment of a multiple sclerosis patient need not be enabled. As such, the grounds for rejection due to the allegation that the specification "fails to provide an adequate enabling disclosure for practicing such method of treatment," is improper and must be withdrawn.

As set forth in the claims, the method is performed by screening a multiple sclerosis patient for the presence of an human leukocyte antigen (HLA)-DR2 haplotype. Identifying an (HLA)-DR2 haplotype in such a patient in turn predicts therapeutic efficacy. Accordingly, it is the screening for the presence of an human leukocyte antigen (HLA)-DR2 haplotype that must satisfy the enablement requirement under 35 U.S.C. §112, first paragraph. In this regard, (HLA)-

DR2 haplotypes including, for example, DRB1*1501 and DRB1*15021, were known in the art at the time of the invention. Identifying the presence of these and other (HLA)-DR2 haplotypes can be performed by methods known in the art at the time of the invention.

In sum, as screening for an human leukocyte antigen (HLA)-DR2 haplotype was known in the art at the time of the invention, the claims are adequately enabled. As such, the rejection under 35 U.S.C. §112, first paragraph must properly be withdrawn.

The rejection of claims 18 to 20 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is respectfully traversed. The Examiner indicates that claims 18-20 allegedly "fail(s) to correspond in scope with that which applicant(s) regards as the invention." The claims have also been rejected due to several allegedly indefinite terms.

Applicants first respectfully direct the Examiner's attention to M.P.E.P. §2173.02, particularly that "[t]he examiner's focus during examination of claims for compliance with....35 U.S.C. §112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available." [Emphasis added] Furthermore, "latitude in the manner of expression and the aptness of terms should be permitted." The determining factors is "whether the claim apprises one of ordinary skill in the art of its scope." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000)

Here, claims 18 to 20 are clear and definite as originally filed because the skilled artisan would be apprised of the claimed subject matter. In particular, as to the nature of SEQ ID NO:1, this sequence identifies this 170 amino acid human myelin basic protein (MBP) in the substitute Sequence Listing submitted herewith. As discussed above, the substitute Sequence Listing including the 170 amino acid MBP does not introduce new matter because, *inter alia*, this MBP sequence was disclosed in the parent application, which was expressly incorporated by reference in the subject application (see Exhibit A). As such, claims 18-20 correspond in scope with that which applicant(s) regards as the invention.

As to the various abbreviations, in view of the specification and knowledge in the art the skilled artisan would understand the meaning of the abbreviations used. In particular, in view of the specification the skilled artisan understands that the abbreviation "MS" means "multiple sclerosis," and in view of the art that "HLA" means "human leukocyte antigen." The skilled artisan also understands that in the relevant art "DR" refers to an HLA class II subregion where such antigens are located (see, for example, Harrison's "Principles of Internal Medicine," McGraw-Hill, New York). Polymorphisms are known to occur in DRs, and the skilled artisan also knows that DRB1*1501 and DRB1*15021 refer to particular class II polymorphic alleles. Thus, given that the skilled artisan understands the meaning of "MS," "HLA," "DR," "DRB1*1501" and "DRB1*15021," claims 18 to 20 are clear and definite as originally filed.

In any event, solely in an effort to comply with the Examiner's request, and not because any of the terms are in any way vague or indefinite, claim 20 has been amended for reasons unrelated to patentability to recite "multiple sclerosis," and claims 18 and 19 have been amended to recite "human leukocyte antigen." Because the meaning of "DR" and the "DRB1*1501" and DRB1*15021" polymorphisms are understood by the skilled artisan, and their meaning cannot be conveniently conveyed by other language, Applicants need not amend the claims in this respect to satisfy 35 U.S.C. §112, second paragraph.

As to the term "about," the Federal Circuit has held that including terms of degree does not automatically render the claim indefinite. *Seattle Box Co., v. Industrial Crating & Packing*, Inc. 731 F.2d 818 (Fed. Cir. 1984). In this regard, the skilled artisan, in view of the specification, would understand the meaning of the term "about" in the context of amino acid length. For example, the specification discloses that the peptides can vary by single amino acid increments, and in one embodiment, the peptide can be a 26 amino acid residue (see, for example, page 13, lines 12-13, and lines 17-18). Thus, in view of this disclosure, the skilled artisan would know that the phrase "about 8 to about 25 amino acids" would include peptides having 7 or 26 amino acids.

In any event, solely in an effort to comply with the Examiner's request, and not because the term "about" is in any way vague or indefinite, claim 18 has been amended for reasons

unrelated to patentability to delete the term "about." Accordingly, in view of the amendment, this grounds for rejection are moot.

In sum, in view of the fact that one skilled in the art would understand the meaning of the various terms used in claims 18 to 20 and, therefore, be apprised of the scope of the claims, the claims are clear and definite. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

II. REJECTION UNDER 35 U.S.C. §102(a)

The rejection of claims 18 to 20 under 35 U.S.C. §102(e) as allegedly anticipated by Gaur *et al.* (U.S. patent No. 6,379,670) is respectfully traversed.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration (In re Spada, 15 USPQ 2d 1655 (Fed. Cir. 1990), In re Bond, 15 USPQ 2d 1566 (Fed. Cir. 1990).

As set forth above, the subject application was filed March 20, 2001, and is a continuation of application Serial No. 09/055,263, filed April 6, 1998. As such, the subject application has an earlier priority date than Gaur *et al.* (U.S. Patent No. 6,379,670, filed August 19, 1999) and, therefore, Gaur *et al.* (U.S. Patent No. 6,379,670) is not available as prior art under 35 U.S.C. §§102 or 103 against the claims of the subject application. Accordingly, the rejection under 35 U.S.C. §102(e) must properly be withdrawn.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 18 to 25 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any additional fees, or make any credits, to Deposit Account No. 03-3975.

Respectfully submitted,

Date: 12-1-03

Robert M. Bedgood, Ph.D.
Reg. No. 43,488
Agent for Applicant

PILLSBURY WINTHROP LLP
11682 El Camino Real, Suite 200
San Diego, CA 92130-2593
Telephone: (858) 509-4065
Facsimile: (858) 509-4010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: **Warren, et al.**

Examiner: **Chernyshev, O.**

Serial No.: **09/813,463**

Group Art Unit: **1653**

Filed: **March 20, 2001**

Docket: **098810/027 8740**

For: **PEPTIDE SPECIFITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS**

STATEMENT UNDER 37 C.F.R. § 1.821 (f) and (g)

Commissioner of Patents
Washington, D.C. 20231

Sir:

In connection with the Sequence Listing submitted concurrently herewith, the undersigned hereby states that:

1. The paper copy of the Sequence Listing, submitted in accordance with 37 CFR 1.825(b), is the same as the computer readable copy of the Sequence Listing; and

2. The content of the Sequence Listing information recorded in computer readable form is identical to the paper copy of the Sequence, submitted in accordance with 37 C.F.R. §1.825(a), does not include any new matter.

Respectfully submitted,

PILLSBURY WINTHROP LLP

Date: 12-1-03

Robert M. Bedgood
Reg. No. 43,488

PILLSBURY WINTHROP LLP
11682 EL CAMINO REAL, SUITE 200
SAN DIEGO, CA 92130

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being mailed with the United States Postal Services on the date shown below in an envelope addressed to the United States Patent and Trademark Office, Attn: Box Sequence, P.O. Box 1450, Mail Stop Sequence Listing, Alexandria, VA 22313-1450

Dated: 12/1/03 By: Pat Munoz

SEQUENCE LISTING

<110> THE GOVERNORS OF THE UNIVERSITY OF ALBERTA
WARREN, KENNETH G.
CATZ, INGRID

<120> PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS

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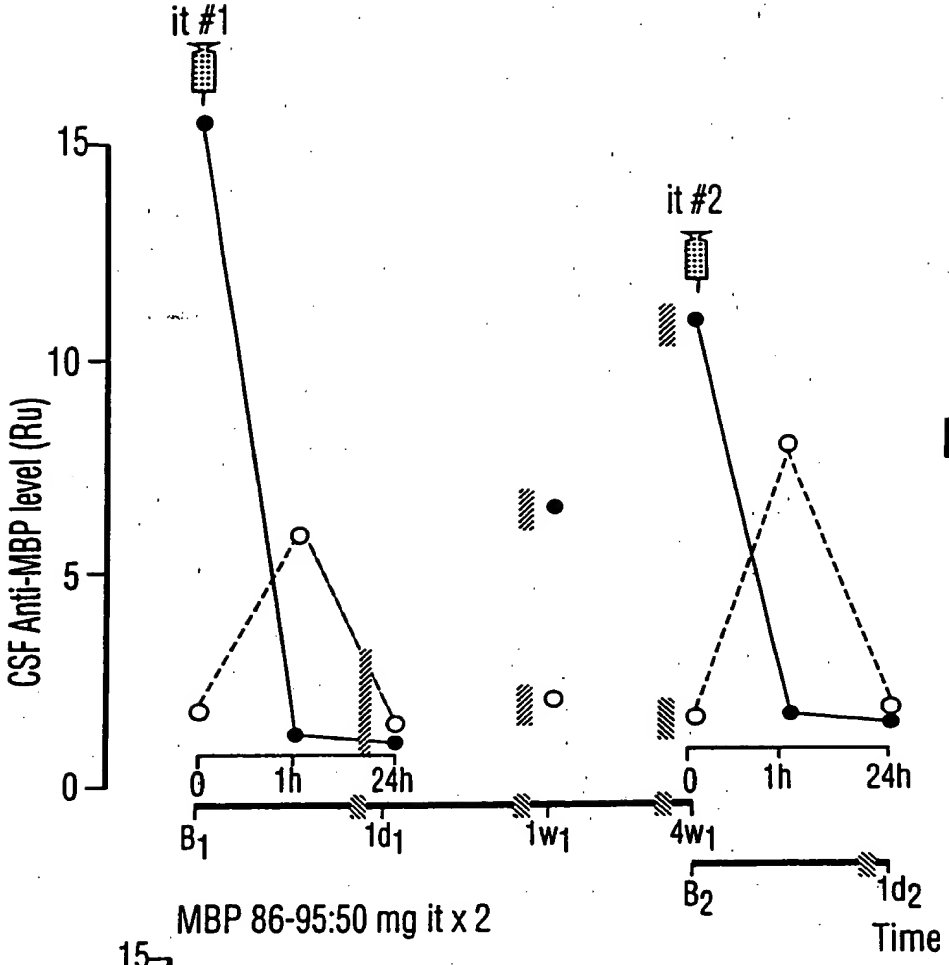
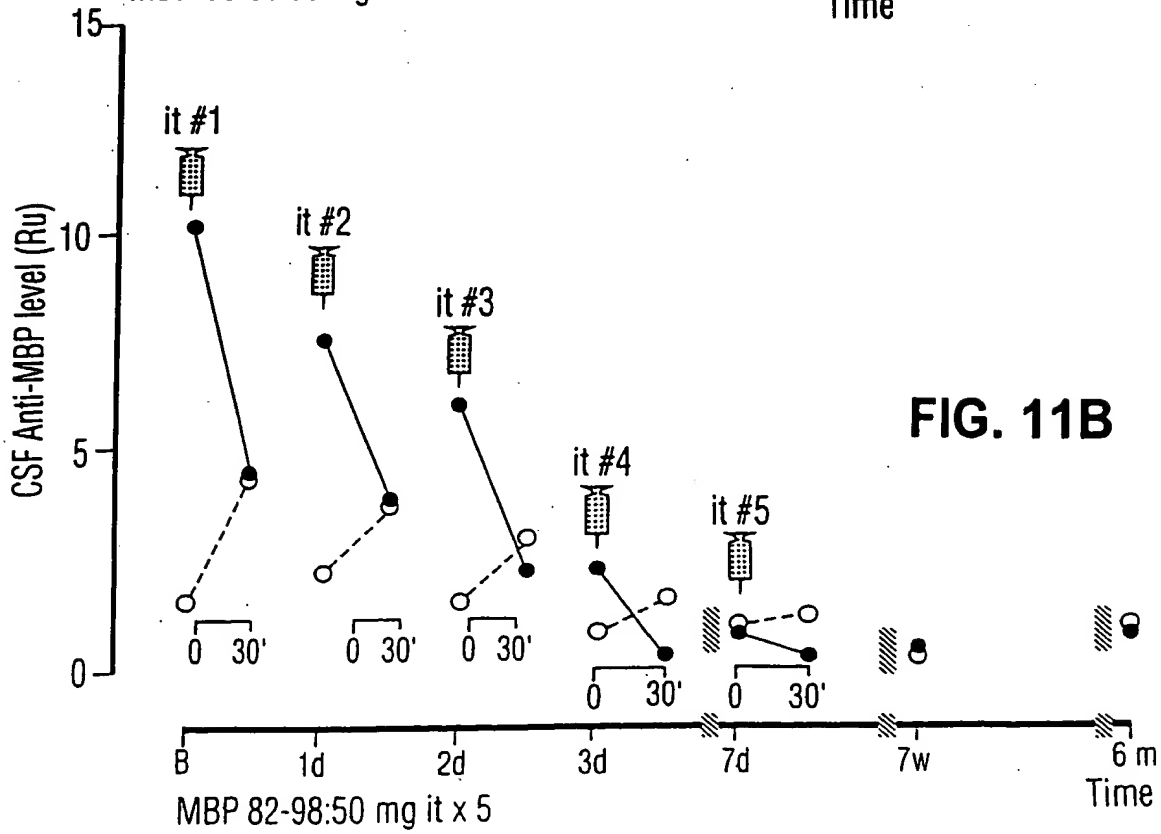


FIG. 11A



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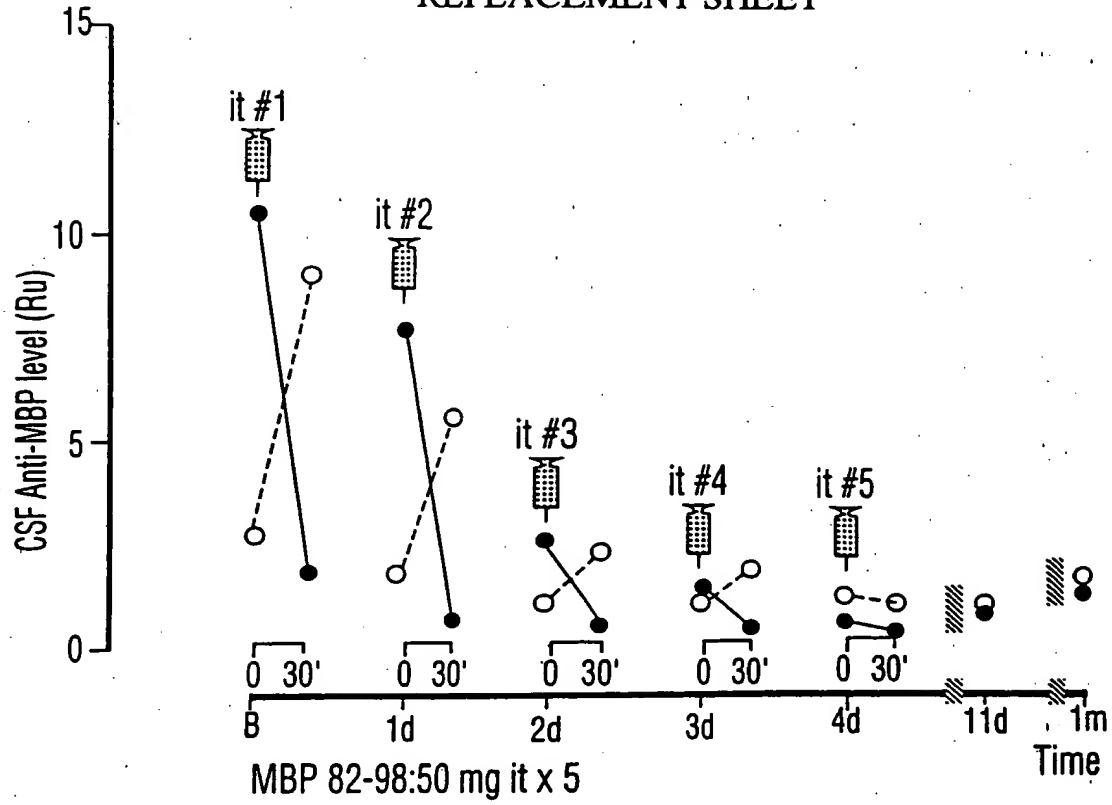

FIG. 11C

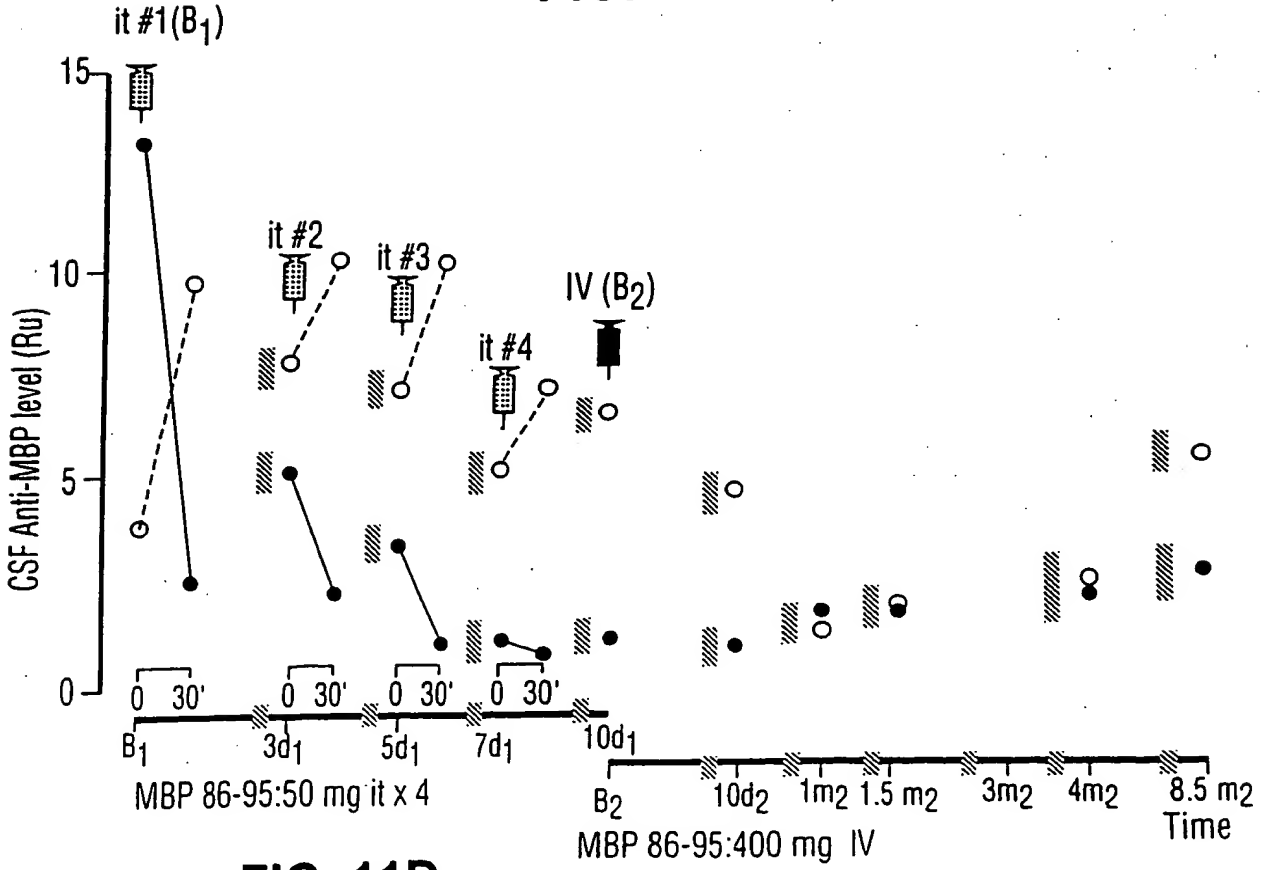

FIG. 11D

EXHIBIT A

Certificate of Express Mailing Under 37 C.F.R. §1.10

ıereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being mailed a "Express Mail Post Office to Addressee" service of the United States Postal Services (Express Mail Label No. EL 841)7 591 US) on the date shown below in an envelope addressed to the Commissioner of Patents and Trademarks, U.S. atent and Trademark Office, Washington, D.C. 20231.

)ated:_____ **By:**_____
Jane K. Babin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR FILING
(RULE 53(b)(1))

For Design or Utility Applications **(DO NOT USE FOR CIPs)**

Rule 53(b)(1) PATENT APPLICATION:
☒ Continuation)
) application under 37 CFR 1.53(b)(1)
☐ Divisional)
Application under 37 CFR 1.53(b)(1)
of pending prior application of

Group Art Unit: 1653

Examiner: A. Davenport

Inventor(s): Warren et al.
Parent Appln. No.: 09 (Series Code ⇧) | 055,263 (Serial No. ⇧)

Atty. Dkt. P 278740 (New M#) | _____ (Client Ref)

Parent Filed: April 6, 1998
This Appln. Filed: March 20, 2001

Title: PEPTIDE SPECIFICITY OF ANTI-MYELIN BASIC PROTEIN AND THE ADMINISTRATION OF MYELIN BASIC PROTEIN PEPTIDES TO MULTIPLE SCLEROSIS PATIENTS

Hon. Commissioner of Patents
Washington, DC 20231

Date: March 20, 2001
(Parent Matter No. 276378)

Sir:

To effect the above-requested filing today:

1. **Attached** is a copy (**which must be filed**) of the prior application, including:

☒ Abstract
☒ Specification and claims (48 pages) (**must be attached**)
☒ Drawings (**must be attached if originally filed**): 19 sheet(s)/set: ☐ 1 set informal; ☒ Formal of size ☐ A4 ☒ 11"

1A. Always X one box, only:
(1) ☒ Copy of Signed declaration or oath as originally filed in prior application attached
(2) ☐ NO declaration or fee is enclosed; therefore, this is a filing under Rule 53(f).

2. ☐ This application is hereby filed by less than all of the inventors named in the prior application. Petition is hereby made requesting deletion as inventor(s) of the following who is/are **not** inventor(s) of the invention being claimed in this application (DELETE THE FOLLOWING INVENTOR(S)):

1. _____ 2. _____
3. _____ 4. _____
5. _____ 6. _____
7. _____ 8. _____

2.5 THE INVENTOR(S) FOR THIS NEW APPLICATION IS(ARE):

1. Kenneth G. Warren
2. Ingrid Catz
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

3. The entire disclosure of the prior application is considered as being part of the disclosure of the accompanying application and is hereby incorporated therein by reference thereto.

4. ☐ Priority is claimed under 35 U.S.C. 119/365 based on filing in _____ (country) of

Application No.	Filing Date	Application No.	Filing Date
(1) _____	_____	(2) _____	_____
(3) _____	_____	(4) _____	_____
(5) _____	_____	(6) _____	_____

a. ☐ _____ (No.) Certified copy/copies attached.
b. ☐ Certified copy/copies previously filed on _____ in U.S. Application No. _____/_____, filed on _____.
series code ⇧ ⇧ serial no.
c. ☐ Certified copy/copies filed during International stage of PCT/ _____/_____.

4. (a) ☐ Domestic priority is claimed from _____/_____, filed _____. PCT/

(b) ☐ Benefit is claimed of Provisional Application No. 60/_____, filed _____.

5. ☒ Prior application is assigned to The Governors of the University of Alberta

by assignment recorded August 19, 1998 (Date) Reel 9391 Frame 0889.

6. ☒ Attached is the following number of Assignments (including original and all later successive ones by different assignors): _____ and respective **new** Cover Sheets. (Do **NOT** file old cover sheets.)

(Assignments in parent **must be refiled** with new Cover Sheets in this continuing application if you want it/them recorded against the continuing application.)

Please return the recorded Assignment to the undersigned.

7. ☒ The power of attorney in the prior application is to John R. Wetherell, Jr., Ph.D.

(Name and Reg. No.)
whose current address is as in item 8 below.

a. ☒ Recognize as associate attorney Jane K. Babin, Ph.D.

(Name, Reg. No. and Address)

8. **Address all future communications to Intellectual Property Group of Pillsbury Winthrop LLP, 50 Fremont Street, San Francisco, CA 94105-2228**

9. ☒ **Amend the specification** by inserting before the first line the sentence:--This is a ☒ continuation ☐ division of Application No. 09/055,263, filed April 6, 1998
series code ⇧ ⇧ serial no.

9. (a) ☐ **Amend the specification** by inserting before the first line: --This application claims the benefit of Provisional Application No. 60/_____, filed _____.--

10. **Small Entity Status** ☐ is Not claimed ☒ is claimed (**pre-filing confirmation required**)

(No.) Small Entity Statement(s) (not essential since 9/8/00) were/are:

☒ filed in above prior application
☐ attached.

etition to extend the life of the above prior application to at least the date hereof
☐ is being concurrently filed in that prior application (Use Form PAT-111).
☐ was previously filed in that prior application (Check length of prior extension).
☐ is not necessary for copendency (Double check before X'ing this box).

☐ **INFORMATION DISCLOSURE STATEMENT:** Attached is Form PTO-1449 listing all of the documents cited by Applicant and the PTO in the parent application(s) relied upon under 35 USC 120 and referenced in item 9 above. Per Rule 98(d) copies of those documents are not required now. Please consider those documents and advise that they have been considered in this new application as by returning a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column per MPEP 609..

☐ Attached is a Rule 103(a) Petition to Suspend Action.

☐ **PRELIMINARY AMENDMENT to be entered before fee calculation:** (Do not make amendments here except for correction of improper multiple dependencies or cancellation of whole claims or multiple dependencies for purpose of reducing the filing fee per MPEP §§ 506 and 607; do not cancel all claims).

FILING FEE

THE FOLLOWING FILING FEE IS BASED ON
->->->->CLAIMS AS FILED AND CHANGED BY PRELIMINARY AMENDMENT IN ITEM 14<-<-<-<-

NOTE: If box 1A2 is X'd, do not pay fees, but leave lines 15-22 and 27-32 blank.

PTO: PLEASE NOTE CLAIM CANCELLATIONS IF BOX 14 ABOVE IS X'D.

				Large/Small Entity		Fee Code
15. Basic Filing Fee				Design Application	\$320/\$160	+355	106/26 101/201
16. Basic Filing Fee				Utility Application	\$710/\$355	+0	103/203
17. Total Effective Claims	15	minus 20 =	0		x \$18/\$9	+40	102/202
18. Independent Claims	4	minus 3 =	1		x \$80/\$40	+0	104/204
19. If any proper multiple dependent claim (ignore improper) is present,					\$270/\$135	\$395	
20.					Subtotal =	+0	122
21. If "petition" box 13 above is X'd, add petition fee.				\$130		+40	581
21A. If box 6 above is X'd, add Assignment recording fee				\$ 40			
TOTAL FILING FEE ATTACHED =						\$435	

(carry forward to Item 31)

22.

23. ☒ ATTACHED: Assignment Recordation Cover Sheet

24. ☐ Preliminary Amendment attached (to be entered after assigning Appln. No.)

25. ☐ See **NONPUBLICATION REQUEST** under Rule 213(a) attached (Pat-258)

26. **ADDITIONAL FEE CALCULATION FOR PRELIMINARY AMENDMENT PER BOXES 24/25**

	Claims remaining after amendment		Highest number previously paid for		Present Extra		Large/Small Entity		Additional Fee	File Code
27. Total Effective Claims	*	minus **	20	=	0	x	$18/$9	=	$ 0	(103/203)
28. Independent Claims	*	minus ***	3	=	0	x	$80/$40	=	+ 0	(102/202)
29. If amendment enters proper multiple dependent claim(s) into this application for the first time, add (per application)							$270/$135		+ 0	(104/204)
30.							ADDITIONAL FEE		$ 0	
31.							plus FEE from item 22 on page 3		+ 0	
32.							TOTAL FEE ATTACHED		$ 0	

33. *If the entry in this space is less than a entry in the next space, the "Present Extra" result is "0"

34. **If the "Highest number previously paid for" (see item 17 above) is less than 20, write "20" in this space

35. If the "Highest number previously paid for" (see item 18 above) is less than 3, write "3" in this space

Our Deposit Account No. 03-3975
Our Order No. 98810 (C#) | 278740 (M#)

CHARGE STATEMENT: Upon the filing of a Declaration pursuant to Rule 60(b) or 60(d), the Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown above for which purpose a duplicate copy of this sheet is attached.
This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed.

Pillsbury Winthrop LLP
Intellectual Property Group

50 Fremont Street
San Francisco, CA 94105-2228

Tel: (415) 983-1000
JKB/pm
Atty./Sec.

By Atty: John R. Wetherell, Jr., Ph.D **Reg. No.** 31,678

Sig: _____

Fax: (415) 983-1200
Tel: (858) 509-4022

NOTE No. 1: File this Request in duplicate with 1 postcard receipt (PAT-103) & attachments
NOTE No. 2: Is extension in parent necessary for copendency? DOUBLE CHECK Item 11 above. If yes, printout Pat-111 and head it in parent.